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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/781,296	01/13/1997	JOHN B. HARLEY	OMRF161	8073
23579	7590	01/16/2004	EXAMINER	
PATREA L. PABST HOLLAND & KNIGHT LLP SUITE 2000, ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET, N.E. ATLANTA, GA 30309-3400			CLOW, LORI A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

08/781,296

**Applicant(s)**

HARLEY ET AL.

**Examiner**

Lori A. Clow, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-40 is/are pending in the application.
- 4a) Of the above claim(s) 30-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 September 2003 has been entered.

Applicant has raised several issues regarding the prosecution of the instant application. In order to fully respond, each argument will be addressed below in the order presented in the response dated 15 September 2003. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 27-40 are currently pending.

#### Information Disclosure Statement

Applicant states the following:

1. *There is no signed PTO 1449 for the information disclosure statement mailed 3 December 1998.*

This IDS was considered on 2 March 1999, as indicated in the Office Action mailed 17 March 1999.

2. *There is no signed PTO 1449 for the information disclosure statement mailed 14 January 1999.*

After careful review of the file, the examiner was able to find form 1449 submitted 14 January 1999. The form was mailed in the Office Action dated 17 March 1999 and an explanation of the unsigned portions was given. The examiner is including a copy of both PTO 1449's from this action for applicant's record.

3. *There is no signed PTO 1449 for the information disclosure statement mailed 21 June 1999.*

Applicant is correct in this statement. The examiner has located the form 1449 pertaining to the 21 June 1999 IDS. However, the references filed with the IDS do not match those listed on the form 1449, therefore the IDS has been placed in the file, but the references cited therein have not been considered. The examiner requests that applicant please re-submit the IDS and the correct references.

#### Priority Claim

Applicant states the following:

1. *The issue of priority also needs to be resolved. Applicants have properly claimed priority to USSN 08/160,604. Applicants have provided the basis for the priority claim. The examiner's response has been to state that the applicants are not entitled to priority. This is clearly improper. If priority is to be denied, the examiner is obligated to fully respond to applicant's basis for the priority claim so that this issue may be fully argued on appeal.*

Applicant is advised to review the Office Action dated 24 June 1998, in which it is indicated that the first application disclosing the administration of EBV or EBV components is 60/091,053. Therefore, the claims directed to administration (28 and 29) are accorded an

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effective filing date of 16 May 1996. This issue has been addressed in several subsequent Office Actions.

In further answer to the priority claim the examiner recognizes that now pending claim 27 is directed to a peptide composition comprising of a peptide selected from SEQ ID NO: 27, as elected in response to the Restriction Requirement of 20 October 1999. US 08/160,604, now US 6,232,522, does not contain SEQ ID NO: 27 and therefore priority is denied.

#### Restriction/Election

Claims 27-40 are pending in this application. Claims 28 and 30-40 are withdrawn from consideration for being directed to a non-elected invention, as stated in several previous Office Actions.

Claims 27-29 and SEQ ID NO: 27 were elected on 28 October 1999. Subsequently, applicant has amended the claims to delete the elected SEQ ID from claim 28. Therefore, claim 28 is withdrawn from consideration until such time claim 28 recites SEQ ID NO: 27.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 29 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the previous Office Actions, the field of autoimmunity is unpredictable and therefore, one of ordinary skill in the art would not be able to extrapolate from the limited examples the scope of the variety of peptides, dosages, and dosing schedules in order to find tolerance inducing regimes. Please refer to the prior Office Actions for the full text of the rejection. Applicant has presented no new arguments.

Applicant argues the utility rejection under the 35 USC 112 heading. However, there are no outstanding rejections under 35 USC 101, therefore the arguments are moot.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 27 remains rejected under 35 USC 102(b) as being clearly anticipated by SEQ ID NO. 4 of Middeldorp (WO 94/06912) and the disclosure of amino acids 430-438.

Claim 27 remains rejected under 35 USC 102(e) as being clearly anticipated by (US 5,965,353) for reasons set forth in the previous office action.

Claims 27 and 29 are rejected under 35 USC 102(e) as being anticipated by Harley et al. (US 6,232,522) for disclosing the exact invention (peptide compositions) as the instant application (see SEQ ID listings beginning with column 27).

Applicant has made no new arguments nor amended the claims to overcome the rejections, therefore all of the rejections are maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27 and 29 remain rejected under 35 USC 103(a) as being unpatentable over Middeldorp (US 5,965,353).

In response to applicant's argument that the prior art does not suggest the claimed invention because there is nothing in Middeldorp that would lead one to identify peptide sequences which are more immunoreactive with autoantibodies and that Middeldorp only

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discloses methods for vaccinating against EBV, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, because the instant specification fails to point out exactly how appellant would administer and specifically utilize the claimed peptides the peptide disclosed in Middeldorp are interpreted as the same peptides as intended for use by appellant.

Middeldorp (US 5,965,353) discloses the exact peptides recited in claim 29 and discloses the treatment of EBV-related disease with those peptides (column 4, lines 59-64).

Pharmaceutical preparations of the peptides are also contemplated. Middeldorp also specifically includes the use of fragments of the peptides which are disclosed at column 5, line 36 to column 6, line 15, which includes the peptide which is identical to the instant SEQ ID NO: 24. By immunizing the subject with a peptide, one tolerizes the subject to the effects of said peptide. Therefore, the suggestion of Middeldorp to immunize with peptides or fragments of SEQ ID Nos. 1 and 6, renders the claimed invention *prima facie* obvious, barring evidence to the contrary.

Applicant has made no new arguments nor amended the claims to overcome the rejections, therefore all of the rejections are maintained.

No claims are allowed.



***Inquiries***

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*

January 11, 2004

Lori A. Clow, Ph.D.  
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*Lori A. Clow*